

Female Urology, Urodynamics, Incontinence, and Pelvic Floor Reconstructive Surgery

Transobturator Tape: Over 10 Years Follow-up



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OBJECTIVES

To assess subjective and objective outcomes in incontinent patients following “out-in” TOT, at >10-year follow-up; to evaluate effect on quality of life and other urinary symptoms, late adverse events and predictive factors for failure.

METHODS

This single-centre prospective study evaluated women with “complicated” or “uncomplicated” stress urinary incontinence (SUI) following “out-i” TOT between 2003 and 2007.

The pre-op work-up comprised: history; pelvic examination; cough stress test; urodynamic study; UDI-6; and King’s Health questionnaires.

Work-up was the same as pre-op plus the Patient Global Impression of Improvement scale with final follow-up in 2017.

RESULTS

One hundred thirty six consecutive patients underwent TOT; at final follow-up (mean 145 months) we evaluated 123. Cure rates: objective: 78.9%; subjective: 62.6%; no significant deterioration in SUI cure rates over time.

Urgency and urgency urinary incontinence (UUI) significantly reduced. Voiding dysfunction increased without urodynamic obstruction. De novo urgency appeared in 7.3% and de novo UUI in 4.1%.

In the 31 uncomplicated SUI patients, the objective cure rate was 87.1% and the subjective cure rate was 72.2%. De novo urgency appeared in 9.7% and de novo UUI in 3.2%.

Nine King’s Health questionnaires domains saw statistically significant improvements.

In univariate analysis, pre-op wet OAB was associated with subjective recurrent SUI ($P < .038$) and parity >2 was associated with objective recurrent SUI ($P = .023$).

We had 5 cases of partial mesh exposure.

CONCLUSION

Cure rates are satisfactory, 10 years after TOT surgery, with good quality of life and few major complications. However, some postoperative symptoms may be caused by long-term treatment failure or by advancing age or another pathology. UROLOGY 129: 48–53, 2019. © 2019 Elsevier Inc.

Increased life-expectancy in western countries amplifies the importance of studying the long-term outcomes of the various treatments for chronic conditions, including urinary incontinence, since these will affect an increasingly elderly population for a longer part of their lives.

It has been widely demonstrated that midurethral slings are the most effective and safest surgical procedures for the management of stress urinary incontinence (SUI).¹

Although the long-lasting benefits of the retropubic route have been adequately evaluated,^{2,3} the long-term

outcomes for the transobturator route need further assessment and there are few studies on “in-out” transobturator tape (TOT),^{4,5} and an absence of studies on “out-in” TOT with a long-term follow-up, which would provide information necessary for proper patient counselling, and would have repercussions on the quality of life (QoL) particularly of longer-living females in developed countries.⁶

The objective of this study is thus to assess the subjective and objective outcomes in incontinent patients who underwent “out-in” TOT, at a follow-up of at least 10 years.

METHODS

This is a single-centre prospective study on women who underwent “out-in” TOT between January 2003 and December 2007 for patients with “complicated” and “uncomplicated” SUI.

Exclusion criteria were as follows: women with a history of radical pelvic surgery; previous pelvic organ prolapse (POP) surgery; comorbidities such as diabetes or neurologic disease; the presence of POP stage 2 or greater.

Declaration of Interest: None.

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All patients underwent a standardized pre-op work-up comprising: urogynecologic history; pelvic examination using the POP-Q classification⁷; standardized cough stress test (CST) performed in the standing position at a bladder volume of 300 mL, or at maximum cystometric capacity if this was less than 300 mL; a conventional urodynamic study (UDS) according to ICS criteria, including uroflowmetry, filling cystometry, Valsalva leak point pressure measurement, and pressure/flow study. It is currently a matter for debate whether pretreatment UDS improves clinical outcomes for “uncomplicated” cases. Irrespective of whether it does or not, we decided to perform UDS on all SUI patients because it may give important information, offering a valuable guide to the surgeon and the patient.⁸

SUI was defined according to ICS standardization and classified according to the Ingelmann-Sundberg scale.⁹ Urinary symptoms were evaluated using the standardized questionnaire UDI-6.¹⁰ Voiding symptoms were evaluated in the structured questionnaire in terms of yes-no questions on hesitancy, slow-stream, intermittency, straining to void, and feeling of incomplete emptying (as defined by ICS), and in UDI-6 question 5, which gives 4 degrees of difficulty in voiding. The King's Health Questionnaire (KHQ) was used to evaluate QoL.¹¹

TOT surgery was performed by an expert surgeon (E.C.) using the out-in transobturator technique originally described by Delorm.¹²

Follow-up visits were scheduled for 1 month, 6 months, 1 year, then annually, with a final visit in September-October 2017. Each visit included a medical history, physical examination, CST, voiding diary, and evaluation of subjective satisfaction. Patients also completed the 2 questionnaires from the preop work out as well as the Patient Global Impression of Improvement scale, a 7-point scale with a range of responses from 1 (very much improved) to 7 (very much worse).¹³ We considered voiding dysfunctions to be present when a patient answered affirmatively at least 2 structured questionnaire questions and also answered “moderately” or “greatly” to question 5 of UDI-6. Repeat UDSs were performed when women complained of de novo symptoms and irrespectively at final follow-up. The examinations and interviews were performed by urologists who were not involved in the surgical phase of the study.

The severity of complications was classified using both the ICS/IUGA classification of mesh complications¹⁴ and the modified Clavien–Dindo classification, which consists of 5 grades, ranging from I (minor risk events) to V (death).¹⁵

Objective cure for SUI was defined as the absence of urine leakage during the CST. Subjective cure was defined by a “no-answer” to question 3 of the UDI-6 questionnaire.

Patient-reported improvement was indicated by the combination of “very much improved or much improved” (score of ≤ 2) on the Patient Global Impression of Improvement scale and a patient-satisfaction score of ≥ 8 , as described by Abdel-Fattah et al.¹⁶

The primary outcome was the subjective and objective SUI cure rates. Secondary outcomes included effect on QoL and other urinary symptoms, late adverse events and predictive factors for failure.

The study was approved by the Ethics Committee of our institution (CEAS Registry No. 8459). All patients signed informed consent.

Statistical analysis was performed using SPSS v.23 and Med-Calv v.18.

We used the chi-square and Mann-Whitney *U* tests to analyze categorical and continuous data; Wilcoxon signed rank tests

were used to compare discrete paired data and the chi-square test for trend to analyze and compare the surgical outcomes during the follow-up.

A logistic regression model and odds ratios (with 95% confidence intervals) were used to assess the possible predictive factors for treatment failure. To determine statistical significance, we performed the chi-square test with a continuity correction per table of 2×2 and, where expected frequencies were insufficient, Fisher's exact test was used.

We considered $P < .05$ to be statistically significant.

RESULTS

From January 2003 to December 2007, 136 consecutive patients underwent TOT. Thirteen patients were lost to follow-up, so we evaluated 123 patients at the last follow-up.

Table 1 shows baseline the demographic information, and clinical and urodynamic characteristics of the study population.

At a mean last follow-up of 145 months (range 121-181 months), the objective cure rate was 78.9% (97 patients) and the subjective cure rate was 62.6% (77 patients).

Table 2 reports outcomes for SUI of the entire sample at 12, 60, and over 120 months after surgery, and shows no significant deterioration in objective and subjective cure rates for SUI over time.

Table 1. Baseline characteristics of the study population

	Study Group (n = 136)
Median age (years, range)	59.01 (33-79)
Body mass index (kg/m ² , mean \pm SD)	27.22 \pm 2.8
Median parity (range)	2 (0-6)
Menopause no. (%)	87 (70.2)
Hormone replacement therapy no. (%)	13 (9.6)
Clinical stress urinary incontinence no. (%)	136 (100)
- grade 1*	37 (27.2)
- grade 2*	73 (53.6)
- grade 3*	26 (19.1)
Voiding dysfunction no. (%)	12 (8.8)
Urgency no. (%)	92 (67.6)
Urge urinary incontinence no. (%)	77 (56.6)
Previous hysterectomy no. (%)	33 (25.2)
- abdominal hysterectomy	24 (17.6)
- vaginal hysterectomy	9 (6.6)
Previous SUI surgery no. (%)	14 (10.2)
- Burch	4 (2.9)
- Marshall-Marchetti	2 (1.5)
- Injectables	6 (4.4)
- Needle suspension	2 (1.5)
Median first desire (mL, range)	150 (107-459)
Median cystometric capacity (mL, range)	405 (177-723)
Normal compliance no. (%)	136 (100)
Detrusor overactivity no. (%)	24 (17.6)
VLPP < 60 cmH ₂ O no. (%)	21 (15.4)
Median PdetQmax (cmH ₂ O, range)	15 (1-58)
Median Qmax (mL/sec, range)	21 (5.0-51.4)
Median PIP (range)	39 (17.7-95.2)
Detrusor undercontractility (PIP < 30) no. (%)	23 (16.9)

* According to Ingelmann-Sundberg scale.

Table 2. Cure rates for SUI at 12, 60, and over 120 months

	Cured no. (%)			P Value for χ^2 Test	
	At 12 mo.	At 60 mos.	At > 120 mo.	12 mos. vs > 120 mo.	For Trend
Objective Outcomes					
Patients	104/131 (79.3)	98/125 (78.4)	97/123 (78.9)	.52	.68 HR 1.98 95% CI 0.41-3.87
Assuming all missing data are failures	104/136 (76.5)		97/136 (71.3)		
Assuming all missing data are cured	109/136 (80.1)		110/136 (80.9)		
Subjective Outcomes					
Patients	87/131 (66.4)	79/125 (63.2)	77/123 (62.6)	.67	.83 HR 1.13 95% CI 0.54-4.28
Assuming all missing data are failures	87/136 (63.9)		77/136 (56.6)		
Assuming all missing data are cured	92/136 (67.6)		90/136 (66.2)		

Ten of the failed patients underwent further SUI surgery: 8 underwent Tension-free Vaginal Tape and 2 underwent bulking agent therapy.

Figure 1 shows the outcomes for OAB and VD at 12, 60, and over 120 months.

We had a statistically significant reduction in urgency from 67.6% (92 patients) to 38.2% (47 patients; $P = .041$). In particular, urgency resolved in 58.7% (54/92 patients), persisted in 41.3% (38/92 patients). Urgency appeared de novo in 7.3% of the entire sample (9/123 patients).

Of these 92 patients, 15 had only urgency, and it resolved in 26.7% (4/15 patients) and persisted in 73.3% (11/15 patients).

Of the 92 patients with pre-op urgency, 77 also had urgency urinary incontinence (UUI), and these had a statistically significant reduction in UUI from 56.6% (77 patients) to 31.7% (39 patients) ($P = .021$). In particular, UUI resolved in 55.8% (43/77 patients) and persisted in 44.2% (34/77 patients). UUI appeared de novo in 4.1% of the entire sample (5/123 patients). All patients with OAB symptoms underwent pharmacologic therapy with antimuscarinic or beta3 agonist drugs.

VD increased from 8.8% (12 patients) to 18.7% (23 patients) ($P = .349$). In particular, VD resolved in 58.3% (7/12 patients) and persisted in 41.7% (5/12 patients). VD appeared de novo in 14.6% (18 patients). In only 1 patient was the appearance of de

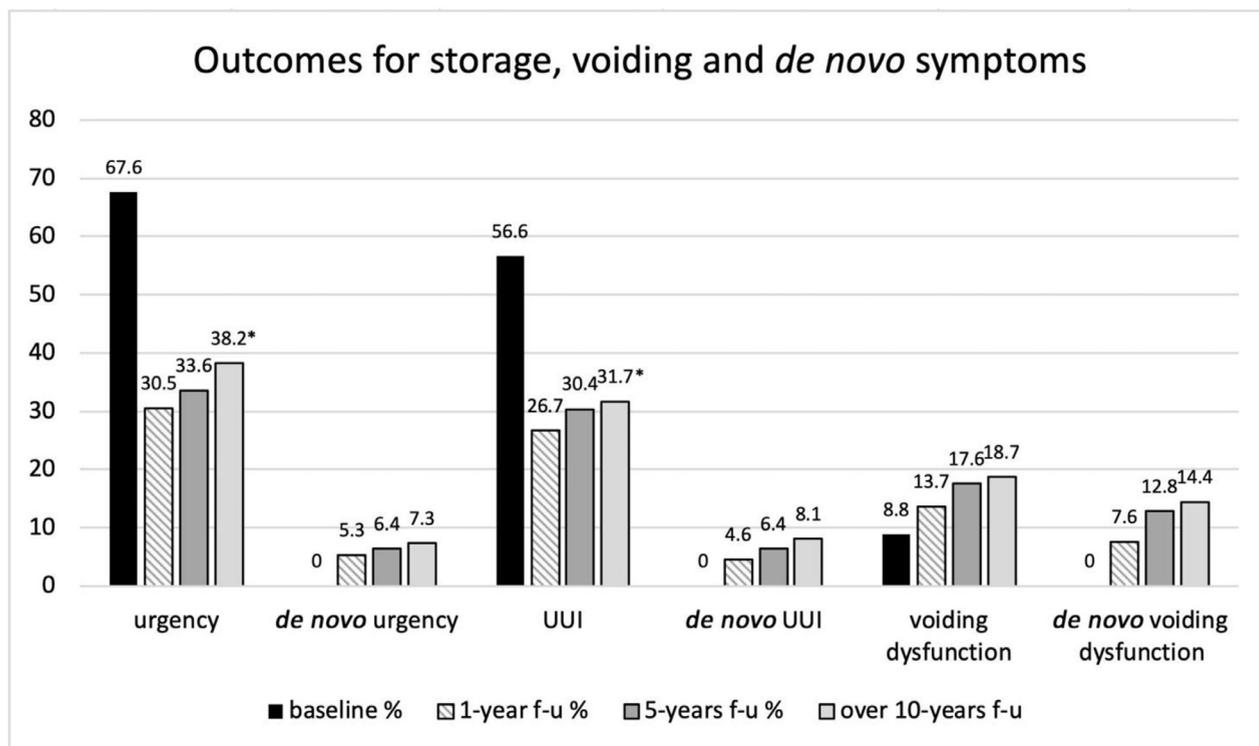
**Figure 1.** Outcomes at 1, 6, and over 10 year for storage, voiding, and de novo symptoms.

Table 3. Univariate analysis of variables potentially involved in the risk of subjective failure for SUI using out-in TOT at over 10 years f-u

	Subjective Outcome		Objective Outcome	
	OR (95% CI)	P	OR (95% CI)	P
Age > 65 years	1.362 (0.520-3.569)	.529	0.837 (0.662-2.934)	.605
Parity > 2	0.421 (0.321-4.612)	.569	3.766 (1.119-11.828)	.023
Menopause	1.098 (0.337-3.201)	.864	0.940 (0.791-2.212)	.318
Overweight (BMI > 25 < 30)	0.719 (0.257-2.011)	.530	0.562 (0.125-3.511)	.579
Obese (BMI > 30)	0.625 (0.190-2.051)	.438	0.884 (0.332-1.176)	.999
Previous SUI surgery	1.405 (0.365-5.406)	.621	1.837 (0.553-2.221)	.409
Pre-op DO	0.777 (0.248-2.437)	.665	0.223 (0.447-2.014)	.999
VLPP < 60 cmH ₂ O	2.367 (0.809-6.925)	.116	0.669 (0.846-3.881)	.580
Wet OAB	2.977 (1.668-13.414)	.038	0.924 (0.374-2.281)	.864
Dry OAB	0.508 (0.048-5.375)	.573	0.719 (0.226-2.815)	.999
Pre-op VD	0.457 (0.142-1.475)	.190	0.778 (0.441-3.774)	.999

Statistical significance was $p < .05$.

novo VD associated with cystocele stage 3. In no patients did we observe a PVR >50 mL. Postoperatively, no urodynamic obstruction was observed using the Blaivas and Groutz nomogram.¹⁷

Considering only the group of 31 patients with pure SUI (25.2% of the entire sample), we observed an objective cure rate of 87.1% (27/31 patients) and a subjective cure rate of 72.2% (23/31 patients). De novo urgency appeared in 9.7% (3/31 patients), and de novo UUI appeared in 3.2% (1/31 patients).

All domains of the KHQ except General Health Perceptions and Sleep/energy saw statistically significant improvements.

Table 3 reports the univariate analysis of factors potentially involved in the risk of recurrent subjective and objective SUI. Only pre-op wet OAB was significantly associated with subjective recurrent SUI ($P = .038$) while parity >2 was significantly associated with objective recurrent SUI ($P = .023$).

Complications were evaluated according to the Clavien-Dindo classification. Twelve patients (9.8%) had de novo VD, who only required observation (Clavien grade I). We had 6 (4.9%) de novo VD, who were treated with alpha-blockers, and we had 9 patients (7.3%) with de novo OAB symptoms, who were treated with antimuscarinics or beta 3 agonists (Clavien grade II). We had 5 cases of partial mesh exposure, which required tape revision (Clavien grade IIIa): in 3 patients at 6-months follow-up, in 1 patient at 2-year follow-up and in 1 patient at 6-year follow-up; none became incontinent. All these patients were examined using cystoscopy to exclude urethral or bladder extrusion and, before undergoing tape revision, they underwent local antibiotic and oestrogen therapy.

The 5 patients with grade III-a complications on the Clavien scale were evaluated further using the ICS/IUGA classification of mesh complications: 2 patients had 2B, T3, S1 exposure; 2 patients had 2B, T4, S2; 1 patient had 3B, T3, S2.

COMMENT

With an objective cure rate of 78.9% and a subjective cure rate of 62.6% over a follow-up of more than 120 months, our study shows that out-in TOT is an effective long-term option for the treatment of SUI.

Prior to ours, no study has been published on the long-term outcomes of "out-in" TOT in SUI women, and only 2 studies have been published on the long-term outcomes of "in-out" TOT. In 2017 Serati et al reported the subjective and objective cure rates of TVT-O, in a group of 160 women with urodynamically proven pure SUI with a

follow-up of 10 years and showed an objective outcome of 92% and a subjective outcome of 97%.⁵ In 2018 Zang et al published data on a group of 73 uncomplicated SUI patients who underwent TVT-O with a follow-up of 12 years and reported an objective cure rate of 82.2% and a subjective satisfaction rate of 80.8%.¹⁸

Our results are lower than Serati and Zang, which we attribute to fact that we included both patients with pure SUI and patients with SUI and OAB, while they both studied only pure SUI patients. We chose to include also SUI patients with OAB because there are twice as many with OAB as without.¹⁹

In addition to satisfactory results for the correction of SUI, we observed a statistically significant reduction in storage symptoms, while voiding symptoms increased without reaching statistical significance.

Analysis of our KHQ results shows that TOT surgery has a good impact on QoL with a median total score of 466.3 preoperatively and 169.3 postoperatively.

Complications occurred in 26.1% of cases at last follow-up. We observed de novo urgency in 7.3% and de novo UUI in 4.1% of the sample. No case of de novo VD was associated with outlet obstruction. These percentages are lower than those reported by Serati (14%) and Zhang (12.3%) for patients with pure SUI who underwent TVT-O.^{3,18}

Note that an increase in de novo symptoms is to be expected with the increase in age of the sample as elderly patients are more prone to storage symptoms.²⁰ We observed an escalating increase in the incidence both de novo urgency and UUI at 1-year, 6-year, and over-10-years follow-up visits (Fig. 1).

We had 5 cases of partial mesh exposure (4.1%), which needed mesh revision, which is similar to Zang (5.5%) but higher than Serati, who had no cases. The interval between tape placement and tape exposure ranged from 6 months to 6 years. The need for a long-term follow-up is borne out both by this extensive range and by the escalating incidence of de novo symptoms described in the previous paragraph.

The results of our univariate analysis show that only pre-op wet OAB was significantly associated with subjective recurrent SUI ($P = .038$) and that parity >2 was

significantly associated with objective recurrent SUI ($P = .023$). Our results concur with data in the literature. Gleason et al compared the outcomes of MUS surgery in women with either pure SUI or mixed urinary incontinence (MUI) and demonstrated a significantly lower success rate in MUI patients compared to those with SUI alone (64% vs 85%, $P < .001$).²¹ Ayhan et al showed that patients with a lower number of pregnancies, and especially those with a lower number of deliveries, had significantly higher success rates following SUI surgery.²² This association between parity and lower cure rates is to be expected: the main cause of sling failure is an incorrect sling position, and it is more difficult to position the sling correctly on the shortened urethra caused by a greater number of pregnancies.²³

The other pre-op factors we looked at—demographic, anamnestic, clinical, or urodynamic characteristics—did not indicate any risk factor for failure.

We were particularly interested to evaluate the relationship between DO or dry OAB and recurrence of SUI since some authors think that the presence of OAB symptoms or DO may reduce success rates of SUI surgery.²⁴⁻²⁶ We found no relationship between these variables and the recurrence of SUI. This confirms the finding of a previous study by our group on patients with MUI and prevalent SUI who underwent TOT: we found that DO was associated with odds ratios of 0.17 for the persistence of SUI and of 0.37 for the persistence of UUI.²⁷

The strengths of our study are as follows: (1) this is first paper evaluating “out-in” TOT with a long-term follow-up; (2) the sample is sufficiently large; (3) we performed UDSs preoperatively on all patients without distinguishing between patients with pure SUI and those with both SUI and OAB since it has been demonstrated that a UDS provides new information about uncomplicated SUI patients in 40% of cases, rules out a voiding dysfunction in 13.4% of cases and changes the consequent management in 11% of cases¹⁹; (4) the postoperative complications, subjective satisfaction, and objective cure rates were comprehensively evaluated with standardized methods; (5) we used questionnaires, both pre- and postoperatively that were validated in our language. The limitation of the study was the lack of evaluation of sexuality but, when this study started, there was no questionnaire on sexuality validated in our language.

CONCLUSION

Our study demonstrates that in the period of 10 or more years after TOT surgery, cure rates may still be considered broadly satisfactory, with a good impact on QoL and a low rate of major complications. However, it is difficult to ascertain whether, 10 years or more after surgery, some postoperative symptoms are primarily caused by long-term treatment failure, or by more general factors like advancing age or the development of another pathology.

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